

## United States Patent and Trademark Office

cla

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

| APPLICATION NO.  | FILING DATE     | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.   | CONFIRMATION NO |
|--|-----------------|----------------------|-----------------------|-----------------|
| 09/836,544   | 04/17/2001      | Brian Seed           | 11-88L                | 6823            |
| 23713  | 7590 06/08/2005 |                      | EXAM                  | INER            |
| GREENLEE WINNER AND SULLIVAN P C<br>4875 PEARL EAST CIRCLE |                 |                      | DIBRINO, MARIANNE NMN |                 |
| SUITE 200  | EAST CIRCLE     | ,                    | ART UNIT              | PAPER NUMBER    |
| BOULDER, CO 80301  |                 |                      | 1644                  |                 |

DATE MAILED: 06/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|   | Application No.  | Applicant(s)            |  |  |  |  |
|---|--|-------------------------|--|--|--|--|
|   | 09/836,544   | SEED ET AL.             |  |  |  |  |
| Office Action Summary   | Examiner   | Art Unit                |  |  |  |  |
|   | DiBrino Marianne   | 1644                    |  |  |  |  |
| The MAILING DATE of this communication app  |  |                         |  |  |  |  |
| Period for Reply  |  |                         |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |  |                         |  |  |  |  |
| Status  |  |                         |  |  |  |  |
| 1) Responsive to communication(s) filed on 12/3/  | Responsive to communication(s) filed on <u>12/3/01, 7/7/01, 9/25/01</u> .  |                         |  |  |  |  |
| 2a) This action is <b>FINAL</b> . 2b) ⊠ This  |  |                         |  |  |  |  |
| 3) Since this application is in condition for allowar   | ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the ments is |                         |  |  |  |  |
| closed in accordance with the practice under E  | x parte Quayle, 1935 C.D. 11, 45   | 3 O.G. 213.             |  |  |  |  |
| Disposition of Claims   |  |                         |  |  |  |  |
| 4)⊠ Claim(s) <u>1,5,7,15-17,19 and 24</u> is/are pending in the application.  |  |                         |  |  |  |  |
| 4a) Of the above claim(s) <u>5,7,15-17 and 19</u> is/are withdrawn from consideration.  |  |                         |  |  |  |  |
| 5) Claim(s) is/are allowed.   |  |                         |  |  |  |  |
| 6)☐ Claim(s) <u>1 and 24</u> is/are rejected.   |  |                         |  |  |  |  |
| 7) Claim(s) is/are objected to.   |  |                         |  |  |  |  |
| 8)☐ Claim(s) are subject to restriction and/or election requirement.  |  |                         |  |  |  |  |
| Application Papers  |  |                         |  |  |  |  |
| 9) The specification is objected to by the Examiner.  |  |                         |  |  |  |  |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.   |  |                         |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).   |  |                         |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  |  |                         |  |  |  |  |
| 11) The oath or declaration is objected to by the Ex  | aminer. Note the attached Office   | Action or form PTO-152. |  |  |  |  |
| Priority under 35 U.S.C. § 119  |  |                         |  |  |  |  |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).   |  |                         |  |  |  |  |
| a)☐ All b)☐ Some * c)☐ None of:   |  |                         |  |  |  |  |
| 1. Certified copies of the priority documents have been received.   |  |                         |  |  |  |  |
| 2. Certified copies of the priority documents have been received in Application No  |  |                         |  |  |  |  |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage   |  |                         |  |  |  |  |
| application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.   |  |                         |  |  |  |  |
| See the attached detailed Office action for a list of the certified copies not received.  |  |                         |  |  |  |  |
| Attachmont(s)   |  |                         |  |  |  |  |
| Attachment(s)  1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)  |  |                         |  |  |  |  |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date   |  |                         |  |  |  |  |
| 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  Paper No(s)/Mail Date 3/8/02, 7/29/02.  5) Notice of Informal Patent Application (PTO-152)  6) Other:   |  |                         |  |  |  |  |

Art Unit: 1644

## **DETAILED ACTION**

- 1. a. In view of the interview with Applicant's representative on 4/29/05, the previous action mailed 4/21/05 has hereby been vacated, as Applicant's amendment of 1/12/05 provided a SEQ ID NO for the sequence appearing on page 65 of the specification at lines 25-26.
- b. Applicant's amendments filed 12/3/01 and 7/7/01 and Applicant's responses filed 9/25/03 and 7/7/01 are acknowledged and have been entered.
- 2. STIC Systems Branch of USPTO has corrected CRF errors in Applicant's CRF filed 12/3/01. STIC deleted non-ASCII "garbage" at the beginning/end of files.
- 3. Applicant's election with traverse of Group I, SEQ ID NO: 28, the nucleic acid molecule encoding CD27, (claims 1 and 24), in Applicant's responses filed 7/7/01 and 9/25/03 is acknowledged.

The basis for the traversal is that a reasonable number of nucleic acid sequences be searched in one application, up to 10, and that the Patent Office search nucleic acid molecules encoding CD27 and then the protein as related subject matter.

Applicant's arguments have been fully considered but are not persuasive for the following reasons.

It is the Examiner's position that the nucleic acid sequences claimed do not share a high degree of identity and they are encode cell surface antigens that are distinct since each ligand to which each of the said cell surface antigens is specific is not obvious over the other set of ligands. Applicant does not make an admission that the nucleic acid sequences are obvious variants of one another. Since the publication of the Official Gazette Notice in 1996, the DNA and protein databases have grown in size. exponentially. This has had a direct impact upon the USPTO's searching capability. What was once a relatively simple search has now become far more burdensome, due both to performing the computer search and the analysis of the search results. The Official Gazette Notice issued back in 1996 was permissive and not a directive. The Notice stated that up to ten sequences may be allowed. One sequence falls within that range of up to ten sequences. Moreover, a search of SEQ ID NO: 28 would not necessarily identify prior art relevant to the examination of other SEQ ID NO claimed. Further it is doubted that Applicant would readily accept rejection of SEQ ID NO: 28 in view of prior art which reads upon the other SEQ ID NO claimed. Clearly different searches and issues are involved in the examination of each group. Thus the searches are not coextensive and search of more than one sequence would be burdensome.

Page 2

Art Unit: 1644

With regard to searching the protein sequence as well as the nucleic acid sequence, Applicant states that "Applicants make no admission that a nucleic acid and the encoded protein are obvious variants of one another." It is the Examiner's position that (1) The inventions are independent (see MPEP\_802.01, 806.04, 808.01) or distinct as claimed (see MPEP\_806.05 - 806.05(I)); and (2) There is a serious burden on the Examiner if restriction is not required (see MPEP\_803.02\_806.04(a) - (j), 808.01(a) and 808.02). Regarding undue burden, the M.P.E.P.\_803 (July 1998) states that: □For purposes of the initial requirement, a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search.

The restriction requirement enunciated in the previous Office Action meets this criterion of serious burden and therefore establishes that serious burden is placed on the Examiner by the examination of additional groups. The inventions are distinct for reasons elaborated in paragraphs 2 and 3 of the Office Action mailed 7/2/03.

## The requirement is still deemed proper and is therefore made FINAL.

Accordingly, claims 5, 7, 15-17 and 19 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to non-elected Inventions.

Claims 1 and 24 are currently being examined only to the extent that they read on elected Group I, a cloned cDNA sequence encoding a cell surface antigen that is CD27 (SEQ ID NO: 28). Applicant is reminded to amend claim 1 to delete limitations drawn to non-elected groups.

- 4. Applicant is required to amend the specification to list the appropriate SEQ ID NOS for sequences disclosed in the specification (for example, in the Brief Description of the Drawings for Figures 2A-B, 4A, 7A, 8A-B, 9A-B, 10A1-10A2, 11A-C, SEQ ID NO for amino acid sequences are required in addition to those already provided for nucleic acid sequences appearing in the said Figure descriptions). See 37 C.F.R. 1.821(d).
- 5. The disclosure is objected to because of the following informalities:
- a. In the Brief Description of the Drawings for Figures 11A-C, the figures are actually disclosed to be Figures 10A1-10A2 on the figures, and actual Figure 10B matches the brief description of the drawings for "Figure 10C". There is no figure 10C in the application.
- b. The address for ATCC on page 25 of the specification at lines 11-13 is incorrect. The current address for American Type Culture Collection is 10801 University Boulevard, Manassas, VA 20110-2209.

Appropriate corrections are required.

Application/Control Number: 09/836,544

Art Unit: 1644

6. The following is a quotation of the second paragraph of 35 U.S.C. 112: The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Page 4

- 7. Claims 1 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- a. Claim 1 is indefinite in the recitation of "CD27(SEQ ID NO: 28," because it is not clear what is meant, i.e., the second parentheses is missing after "28".
- b. Claim 24 is indefinite in the recitation of "Substantially pure cDNA" because it is not clear what is meant. It is suggested that Applicant amend said claim to recite Isolated cDNA.
- 8. For the purpose of prior art rejections, the filing date of the instant claims 1 and 24 is deemed to be the filing date of the instant application, i.e., 4/17/01, as the SEQ ID NO: 28 disclosed in the instant application is not disclosed in the parent applications. SEQ ID NO: 28 in the instant application has a different sequence than that in the 07/983,647 parent application, and a different sequence from that in Table 5 (disclosed to be CD27 encoding nucleic acid) in parent application serial nos. 07/533,759 and 07/498,809. For example, two differences are in nucleic acid numbers 1103 and 1104 that are "C" and "T", respectively, in the instant application, and "G" and "C", respectively, in the parent applications. In addition, the sequences in the parent applications are of different length than the SEQ ID NO: 28 of the instant application. Parent application serial no. 07/379,076 has no support for SEQ ID NO: 28 of the instant application. The Examiner was not able to obtain the file at this time to search parent application serial no. 07/160,416.

In addition, because of the difference in sequences, the instant application is not a divisional application of parent application serial no. 07/983,647.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Application/Control Number: 09/836,544

Art Unit: 1644

10. Claims 1 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,607,879 B1.

US 6,607,879 B1 discloses an isolated molecule of mRNA or cDNA for SEQ ID NO: 28 of the instant application, that is CD27 or SEQ ID NO: 1027 of US 6,607,879 B1 (especially column 2 at lines 43-56 and column 59). As regards the limitation "cloned cDNA segment" the product is the same regardless of the descriptor "cloned", and in addition, the molecule disclosed by US 6,607,879 B1 is cloned.

Page 5

11. Claims 1 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2004/0077003 A1 as evidenced by US 6,607,879 B1.

US 2004/0077003 A1discloses an isolated molecule of cDNA for SEQ ID NO: 28 of the instant application, that is CD27 or SEQ ID NO: 1027 of US 2004/0077003 A1 (especially [0138], [0139], claim 5). US 2004/0077003 A1 claims priority to US 6,607,879 B1. As regards the limitation "cloned cDNA segment" the product is the same regardless of the descriptor "cloned", and in addition, the molecule disclosed by US 2004/0077003 A1 is cloned.

Evidentiary reference US 6,607,879 B1 discloses an isolated molecule of mRNA or cDNA for SEQ ID NO: 28 of the instant application, that is CD27 or SEQ ID NO: 1027 of US 6,607,879 B1 (especially column 2 at lines 43-56 and column 59).

12. Claims 1 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,812,339 B1.

US 6,812,339 B1 discloses an isolated/cloned cDNA molecule comprising SEQ ID NO: 28 of the instant application, that is CD27 or SEQ ID NO: 1204 of US 6,812,339 B1 (especially column 9 at lines 33-65, sequence listing). US 6,812,339 B1 has priority to at least 10-20-2000 for SEQ ID NO: 1204 through provisional parent application serial no. 60/241,755.

- 13. The references crossed out in Applicant's Form 1449 filed 3/8/02 and 7/2/02 have not been considered because they can not be located in the parent and unrelated cases sited by Applicant. It would facilitate prosecution if Applicant would submit the said references.
- 14. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware of in the specification.

Art Unit: 1644

15. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Marianne DiBrino whose telephone number is 571-272-0842. The Examiner can normally be reached on Monday, Tuesday, Thursday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Christina Y. Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marianne DiBrino, Ph.D.

Patent Examiner Group 1640

Technology Center 1600

May 26, 2005

CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER

ECHNOLOGY CENTER 1600